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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,324	06/30/2006	V.J. Rajadhyaksha	RAJTM-001US	9111

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,324	RAJADHYAKSHA ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on 16 March 2009.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Status of the claims

Claims 1, 8-10 are pending in the application. Claim 1 has been amended by applicant.

Claims 1, 8-10 are presented for examination on the merits.

New Grounds of Rejection (necessitated by Amendment)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledger (WO 96/01645, cited in the IDS of 1/10/06) in view of Committee on Drugs (Pediatrics, 1997; cited in the IDS dated 01/10/06) and Aston (US 5,506,204).

Ledger teaches a method for treating psoriasis, which reads upon an autoimmune disorder (e.g., page 1, lines 7-22; page 24, lines 1-10 of Ledger. See also instant disclosure, page 10), in a human or veterinary patient, said method comprising administering from 0.5 to 1.5 mg of at least one glycopeptides selected from GMDP and GMDP-A (e.g., claims 1-6, 9-11, 20-21 of Ledger; page 24 of Ledger and Examples). The dosages are to be determined suitable by the clinician or physician subject to that, a daily oral dosage in the range from 0.1 to 100 mg (or per unit dose) may be found acceptable, with a range of 0.5 to 50 mg being preferred. In addition, the duration of administration may be varied. Ledger teaches muramyl peptides “GMDP” and “GMDP-A” may be used either singly or in combination with each other in the invention, topically (e.g., page 25, lines 13-24) and orally (e.g., page 24, lines 10-34).

Ledger does not expressly teach the limitations of claims 8: “administered intranasally”, of claim 9: "administered sublingually" and of claim 10: “administered by buccal administration”.

Committee on Drugs teaches that during the past 20 years advances in drug formulations and innovative routes of administration have been made. The understanding of drug transport across tissues has increased. These changes have often resulted in improved patient adherence to the therapeutic regimen and pharmacologic response. The administration of drugs by transdermal or transmucosal

routes offers the advantage of being relatively painless. Also, the potential for greater flexibility in a variety of clinical situations exists, often precluding the need to establish intravenous access, which is a particular benefit for children (e.g. abstract). Committee on Drugs teach that amongst transmucosal types of administration are nasal mucosal administration, which reads upon "intranasally" as in claim 8 (e.g., page 146, column 2); oral transmucosal comprising "sublingual" and "buccal" administration, as in claims 9-10 (e.g., page 147, columns 1-2).

Aston (US 5,506,204) teaches the administration of GMDP and GMDP-A via nasal and buccal ways for treating septic shock, cachexia and other life threatening inflammatory conditions (e.g., abstract, column 18). Aston taught dosages from 0.1 to 100 mg per day with a range of 0.5mg to 5 mg being preferred (column 18, lines 30-46) and which may be optimized by the clinician. With respect to the limitation of claim 1: "by a route of administration whereby it crosses the nasal, sublingual or buccal mucosa every 36 to 96 hours" please note that such limitation necessarily reads upon nasal, sublingual or buccal administration as instantly taught by Aston. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Ledger by using transmucosal routes of administration such as intranasal, sublingual and buccal. The skilled artisan would have been motivated to do so since the Committee on Drugs reference teaches that these buccal, nasal and sublingual modes of administration are relatively painless, have the potential for greater flexibility in a variety of clinical situations and preclude the need to establish intravenous access which is a particular benefit for children (e.g., abstract, pages 146-147;

Committee on Drugs). There would have been a reasonable expectation of success, given that Aston teaches nasal, buccal and by-tablet administrations are adequate ways of therapeutically administering GMDP and GMDP-A to the patient (e.g., col. 18). The adjustment of particular conventional working conditions (e.g., determining appropriate amounts of precipitating agent and agitation speed within such method) is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. As such, it would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g., dosages to be administered, see, pages 24-25 of Ledger and col. 18 of Aston), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation as evidenced in pages 24-25 of Ledger and col. 18 of Aston. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Marcela M Cordero Garcia/
Patent Examiner, Art Unit 1654

MMCG 05/09